

### **REMARKS**

Reconsideration of the captioned application as amended herewith is respectfully requested.

This amendment is filed concurrently with a Declaration Under 37 CFR 1.132 ("Declaration") and a petition for a **two month extension of time** to extend the date of response to the Office Action from 22 December 2004 to 22 February 2005.

The Office Action:

- a) rejected claims 2 – 11, 13, 16 – 22, 24 – 36, and 73 under 35 USC §103(a) by JP 2-53271 to Okada et al. ("Okada") in view of United States Patent No. 6,139,865 to Friend, et al. ("Friend"), CA 2068366 ("Abstract"), and United States Patent No. 5,958,458 to Norling, et al. ("Norling").

Claims 1, 7, 12, 15, 23, and 37 - 72 were cancelled. Claims 2 – 6, 8 – 11, 13 -14, 16 – 22, 24 – 36, and 73 remain pending in this application after entry of this amendment.

**The Rejection of Claims 2 – 11, 13, 16 – 22, 24 – 36, and 73 under 35 USC §103(a) as Unpatentable Over Okada in view of Friend, Abstract, and Norling Should Be Withdrawn**

Claims 2 – 11, 13, 16 – 22, 24 – 36, and 73 stand rejected under 35 USC §103(a) as unpatentable over Okada in view of Friend, Abstract, and Norling. Applicants respectfully disagree for the reasons that follow.

Okada discloses the use of granules coated by a "protective film," which "protect... the granules so that the functions of the film of the coated granules essentially do not change when it is administered to an individual and so that they are resistant to compressive force when compression is applied." Okada, page 2. One such suitable protective film includes 6.5% hydroxypropyl methyl cellulose and 0.5% of a polyethylene glycol. See Okada, Example 3. Therefore, at best, Okada discloses the use of a film containing hydroxypropyl methyl cellulose and polyethylene glycol in a 13:1 ratio.

By contrast, the invention as presently claimed incorporates a “second coating layer on the surface of the first coating layer, the second coating layer comprised of

- i) a film forming polymer; and
- ii) an anti-grit agent,

wherein the weight ratio of film forming polymer to anti-grit agent in the second coating layer is in the range of about 20:80 to about 80:20” (emphasis added). As disclosed in the Specification at page 5, lines 27 – 29, this coating layer is incorporated into Applicants’ claimed invention in these amounts in order to provide superior texture masking properties to the core.

As requested in the Office Action, Applicants provide further evidence of the superior texture masking properties of the claimed coating at the claimed ratio in the attached Declaration. More specifically, Applicants prepared 4 different coatings by generally using the procedure described in Example 3 of Okada, but varying the ratio of HPMC:PEG from 60:40 to 93:7 in each of the four respective coatings. See Declaration, Paragraph 5. Applicants then coated samples of acetaminophen particles with the coating containing HPMC: PEG in a 80:20 ratio and then separately coated acetaminophen particles with the coating containing HPMC: PEG in a 93:7 ratio as described in Okada. See Declaration, Paragraph 6. Applicants then compared the two samples in a blind taste test. See Declaration, Paragraph 7. As a result of this taste test, Applicants found that a significant majority of the subjects preferred the texture of the samples having a coating with “the weight ratio of film forming polymer to anti-grit agent in the second coating layer ... in the range of ...about 80:20,” over the samples having a coating containing film forming polymer to anti-grit agent in a ratio of 93:7 as disclosed in Okada. See Declaration, Paragraph 7 (Eleven out of 12 persons preferred the less gritty texture of samples coated with 80:20 HPMC:PEG relative to similar samples coated with 93:7 HPMC:PEG). Applicants respectfully submit that this example illustrates the unexpectedly superior texture masking property of the texture masking coating as presently claimed.

Okada neither discloses nor suggests the use of a coating layer for texture masking purposes, but rather teaches the use of films for protecting the granules. Okada further neither discloses nor suggests the use of a coating layer containing a film forming polymer and an anti-grit agent within the claimed ratio. Instead, Okada only illustrates one type of its “protective layer” film in only one example, and the film of that one example uses ingredients that are well

above the range claimed by Applicants. As set forth above, Applicants have clearly shown that this range does not yield a coating having superior texture masking properties. See Declaration, Paragraph 7. Furthermore, Okada fails to disclose or suggest the need or the method for modifying its "protective film," let alone the need or the method for modifying such a "protective film" in order to provide texture masking properties.

The other cited art also fails to disclose or suggest the need or the method for modifying the "protective film" of Okada, let alone the need or the method for so modifying the "protective film" in order to modify it into a coating like the "second coating layer comprised of i) a film forming polymer; and ii) an anti-grit agent, wherein the weight ratio of film forming polymer to anti-grit agent in the second coating layer is in the range of about 20:80 to about 80:20" (emphasis added) as claimed herein. Rather, Friend, the Abstract only exemplify certain components suitable for tastemasking agents, such as those suitable for Applicants "first coating layer comprised of a taste masking agent." (emphasis added) The Office Action further found that Norling teaches ingredients for "mask[ing] the bad tasting active substances," and not coatings for masking texture as claimed.

Therefore, Applicants respectfully submit that if one were to combine Okada with the other cited prior art as proposed in the Office Action, the resulting dosage form would not possess the second coating layer as presently claimed. Because the combination of these references fail to disclose or suggest the claimed invention, "second coating layer comprised of i) a film forming polymer; and ii) an anti-grit agent, wherein the weight ratio of film forming polymer to anti-grit agent in the second coating layer is in the range of about 20:80 to about 80:20" (emphasis added), Applicants respectfully submit that the rejection of independent claims 8, 18, 26, 31, and 73 under 35 USC §103(a) as unpatentable over Okada in view of Friend, Abstract, and Norling has been overcome and should be withdrawn.

Claims 2, 3, 4, 5, 6, 9, 10, 11, 13, and 14, which are dependent upon claim 8 and incorporate all of its limitations therein, are likewise also patentable over the combination of Okada in view of Friend, Abstract, and Norling in view of the above.

Claims 16, 17, 19, 20, 21, and 22, which are dependent upon claim 18 and incorporate all of its limitations therein, are likewise also patentable over the combination of Okada in view of Friend, Abstract, and Norling in view of the above.

Claims 24, 25, 27, 28, 29, and 30, which are dependent upon claim 26 and incorporate all of its limitations therein, are likewise also patentable over the combination of Okada in view of Friend, Abstract, and Norling in view of the above.

Claims 32 - 36, which are dependent upon claim 31 and incorporate all of its limitations therein, are likewise also patentable over the combination of Okada in view of Friend, Abstract, and Norling in view of the above.

### **Conclusion**

It is submitted that the foregoing amendments and remarks place the case in condition for allowance. A notice to that effect is earnestly solicited.

In the event that all of the claims are not in condition for allowance, Applicants respectfully request for an interview with the Examiner before the preparation of the next Office Action.

Respectfully submitted,

By: \_\_\_\_\_

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